

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		Docket Number: 01662/62902	
Application Number 10/789,821	Filing Date February 27, 2004	Examiner Unassigned	Art Unit 1625
Invention Title PROCESS FOR PURIFICATION OF ZOLEDRONIC ACID		Inventors Lifshitz-Liron, et al.	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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Date: 4/5/07

Signature: Georgia Galanis

Sir:

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b). The paragraphs marked below are applicable. It is believed that no fees other than those indicated below are due, but authorization is hereby given to charge any additional fees due, or to credit any overpayment, to **Kenyon & Kenyon LLP, deposit account 11-0600**.

☐ 1. This Information Disclosure Statement is being filed (a) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. §1.53(d), (b) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, (c) before the mailing date of a first Office Action on the merits in the present application, OR (d) before the mailing of a first office action after filing of a request for continued examination. No certification or fee is required.

☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a final action, Notice of Allowance, or any action that otherwise closes prosecution.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ c. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 CFR §1.97(c)(2).

☒ 3. This Information Disclosure Statement is being filed after the mailing date of a final action, Notice of Allowance or an action that otherwise closes prosecution, but before payment of the Issue Fee. Applicant(s) hereby request(s) that the Information Disclosure Statement be considered. Please debit **Kenyon & Kenyon LLP, Deposit Account No. 11-0600** in the amount of \$180.00 in payment of the petition fee under 37 CFR §1.17(p) to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

☐ a. I hereby certify that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in any counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(1).

☐ b. I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 CFR §1.97(e)(2).

☐ 4. Relevance of the non-English language reference(s) is discussed in the present specification.

☐ 5. The references were cited in office actions in counterpart foreign applications. English language version of the foreign corresponding foreign office actions and responses thereto are attached for the Examiner's information.

☐ 6. A concise explanation of the relevance of the non-English language reference(s) appears in the Appendix attached hereto.

☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination of the present application.

☐ 8. This application is one of a series of related applications, identified in the attached Appendix, which are directed to related technical subject matter. The identification of those U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is

respectfully requested to consider the cited applications and the art cited therein during the examination.

☐ 9. The reference(s) was/were cited by or submitted to the Office in parent application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 CFR §1.98(d).

☒ 10. English-language Abstracts of the non-English language references are attached hereto.

☒ 11. Since this application was filed after June 30, 2003, copies of U.S. references are not included.

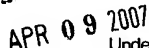
☐ 12. Other. The references cited herein were cited in an International Search Report of _____ provided herewith.

Respectfully submitted,

Date: April 5, 2007

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(Use as many sheets as necessary)

Sheet	1	of	2
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Complete if Known

<i>Application Number</i>	10/789,821
<i>Filing Date</i>	February 27, 2004
<i>First Named Inventor</i>	Lifshitz-Liron, et al.
<i>Art Unit</i>	1625
<i>Examiner Name</i>	Unassigned
<i>Attorney Docket Number</i>	01662/62902

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT BY
APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known

Application Number	10/789,821
Filing Date	February 27, 2004
First Named Inventor	Lifshitz-Liron, et al.
Art Unit	1625
Examiner Name	Unassigned
Attorney Docket Number	01662/62902

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		"Zoledronate Disodium", Drugs of the Future, 2000, 25(3),: 259-268	
		KIECZYKOWSKI et al., 1995, "Preparation of (4-amino-1-hydroxybutylidene)bisphosphonic acid sodium salt, MK-217 (alendronate sodium). An improved procedure for the preparation of 1-hydroxy-1,1-bisphosphonic acids", J. Org. Chem. 60:8310-8312.	
		MULLER et al., "Effects of the Bisphosphonate Zolendronate on Bone Loss in the Ovariectomized and in the Adjuvant Arthritic Rat", Arzneimittelforschung, vol. 48, no. 1, 1998, pages 81-86	
		WIDLER et al., 2002, "Highly potent geminal bisphosphonates. from pamidronate disodium (Aredia) to zoledronic acid (Zometa)", J. Med. Chem. 45:3721-3738.	
		ZHAO et al., 2002, "FDA new drug approvals in 2001", Drug Development 3:400-413.	
		ZHU et al., 2003, "Synthesis of zoledronic acid", Chinese J. New Drugs 12:39-40.	✓

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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